REMARKS

The specification of the present application has been objected to under 35 U.S.C. §132 as introducing new matter into the disclosure.

Applicants respectfully submit that the added material is indeed supported by the originally filed disclosure and that the amendment made to the paragraph bridging Pages 3 and 4 of the specification is not only supported by the originally filed specification but, in addition, corrects obvious typographical mistakes.

As amended, the specification adds the limitation that R may be a C_3-C_6 cycloalkyl group, which is optionally substituted with a straight or branched C_1-C_6 alky group. The Official Action avers that there is no support for R being a C_3-C_6 cycloalkyl group, optionally substituted with a straight or branched C_1-C_6 alkyl group, except for the proviso clause included in the specification at Page 11, lines 9-10.

As previously argued, the specification at Page 11, lines 9-12 provides explicit support for the amendment to the specification made in the paragraph bridging Pages 3 and 4 and in the paragraph bridging Pages 5 and 6. That paragraph unequivocably recites preferred embodiments wherein R is a C_3-C_6 cycloalkyl or an optionally substituted cycloalkyl. That paragraph does not limit the meaning of R of C_3-C_6 cycloalkyl or substituted cycloalkyl to the preferred embodiment wherein n is 0 and R_2 is hydrogen. Indeed, a careful reading of the specification at Page 4, lines 29-30 makes it abundantly clear that it is a condition that when n is 0 and R_2 is hydrogen, R must be C_3-C_6 cycloalkyl. It is not a condition that when R is C_3-C_6 cycloalkyl, n is 0 and R_2 is hydrogen.

If the recitation at Page 11, lines 9 to 12 does not pursuade one skilled in the art that it was the intention of applicants to include C_3-C_6 cycloalkyl, independent of the meanings of n

and R_2, as a meaning of R, that meaning of R is provided by the disclosure in the specification at Page 11, line 24 to Page 15, line 20. Therein examples of preferred compounds of the invention are set forth. Obviously, these embodiments are within the scope of the generic formula I. That many of these compounds encompass compounds where R is C_3-C_6 cycloalkyl, wherein R is $-(CH_2)_n$-R_3 and n is an integer from 1 to 4 establishes that R encompasses the meaning C_3-C_6 alkyl, independent of other limitations.

Of significance also is the misstatement of the case law in the Official Action. The Official Action avers that the numerous specific compounds set forth in the specification and claims which recite compounds which are within the contemplation of formula I of the specification where R is a C_3-C_6 cycloalkyl group, albeit n is not zero and R_2 is not hydrogen, does not provide support for the amendment mentioned above because these specific compounds only support the cited species and not a broad generic claim which encompasses any compound having generic formula I and any meaning of the other variables recited in the specification.

Applicants respectfully submit that the conclusion drawn in the outstanding Official Action does not comport with the case law. It is long been established that where there is no explicit description of the specification of a generic invention, mention of representative compounds may provide an implicit description upon which to base a generic claim. In re Robins, 429 F.2d 452, 166 USPQ 552 (CCPA 1970).

In making this decision, the Court held that the use of representative examples are one way of teaching how to make and/or how to use the claimed invention. As such, amending the specification to generically encompass examples set forth in the specification adds no new matter thereto. Rather, such an addition elucidates the disclosure already provided therein.

The above discussion is applicable to the first ground of rejection of the claims of the present application. Specifically, all but two of the claims submitted for examination in this application, Claims 1-12, 14-19 and 21-23, stand rejected, under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Official Action bases this ground of rejection on the failure of the claims to contain subject matter described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This ground of rejection is lodged in view of the earlier amendment of Claims 1 and 15 to include, as a meaning of R, a C_3-C_6 cycloalkyl group, which is optionally substituted with a straight or branched C_1-C_6 alkyl group.

Applicants reiterate the above remarks contesting the objection to the specification. The amendment to the claims corrects an obvious typographical error in the failure to include C_3-C_6 cycloalkyl as a meaning of R. As emphasized above, the specification provides abundant support for R having the meaning of C_3-C_6 cycloalkyl optionally substituted with a straight or branched C_1-C_6 alkyl group.

A second formal ground of rejection has been imposed in the outstanding Official Action. This formal ground of rejection, directed to Claims 1 to 14, is made under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement.

Specifically, the Official Action avers that the claims contain subject matter which is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and especially use the invention.

The Official Action, applying the criteria set forth In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), submits that the disclosure does not satisfy the enablement requirement based on "undue" necessary experimentation. This conclusion is predicated upon the alleged failure of the instant specification to meet the criteria provided in Wands as a test of whether the specification meets the test of enablement.

The Official Action states that the test is whether or not the treatment of cell proliferative disorders associated with an altered cell dependent kinase activity with the compound of formula I is enabled. Much of the Official Action discussion addresses Alzheimer's disease and viral infections including HIV. Suffice it to say, Claim 2 has been amended and Claim 4 has been cancelled. These amendments result in the focusing upon cancer as the cell proliferative disorder. As such, cancer is the primary cell proliferative disorder to which the compound of formula I is principally addressed.

It is emphasized that enablement of the use of the compound of formula (I) in the treatment of cancer, a cell proliferative disorder, suffices to meet the requirements of the statute, 35 U.S.C. §112, ¶1.

A specification that discloses at least one method of making and using a claimed invention that bears a reasonable correlation to the entire scope of the claim satisfies the enablement requirement. In re Fischer, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. §112. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533, 3USPQ2d 1737, 1743 (Fed. Cir.), cert. denied, 484 U.S. 954 (1987).

The instant invention, directed as it is to the treatment of cancer, employs a class of compounds having structural formula I, is effective based on principles of physiological

activity well established in the art. That is, it is well established in the art that cdk/cyclin kinase inhibitory activity represents a method of restricting the unregulated proliferation of tumor cells. The specification provides evidence that the compounds of formula I are active as cdk/cyclin inhibitors insofar as they provide positive results utilizing an established test, the MultiScreen-PH96 well plate (Millipore), in which a phosphocellulose filter paper is placed at each well bottom allowing binding of positive charged substrate after a washing/filtration step. Suffice it to say, compounds within the contemplation of the present application demonstrated inhibitions of greater than 50%. Thus, the testing procedure for compounds, set forth in the specification at Page 24, line 1- Page 6, line 9, establishes that they are cdkZ/cyclin A activity inhibitors. Such inhibitors are established by well recognized technical literature as being effective as antitumor agents. The specification illustrates one such reference, Webster et al., Exp. Opin. Invest Drugs, 7(6), 865-887 (1998).

It is emphasized that the Official Action discussion of the highly unpredictable nature of cancer therapy is irrelevant to the claims of the present application, limited as these claims are to not merely the treatment of cell proliferative disorders, e.g. cancer, but to such disorders associated with altered cell dependent kinase activity. Succinctly stated, the specification provides support for the treatment of cell proliferative disorders associated with altered cell dependent kinase activity.

It is furthermore noted that the bulk of the discussion in the Official Action is directed to the highly unpredictable nature of treatment of HIV, a viral infection, as well as Alzheimer's disease, which are outside the scope of cell proliferative diseases of amended Claim 2. As stated above, the disclosure of one method of treating cell proliferative disorders, in this case the treatment of cancer, satisfies the requirement for enablement under Fischer.

Reconsideration and rescinding of this formal ground of rejection is deemed appropriate. Such action is respectfully urged.

Two substantive grounds of rejection are imposed in the outstanding Official Action. The first of these is directed to Claims 15-20 and 23, which stand rejected, under the judicially created doctrine of obviousness-double type patenting, as being unpatentable over Claims 1-4, 9 and 15-28 of U.S. Patent 6,387,900 to Pevarello et al.

Claims 15-20 and 23 have been cancelled. As such, this ground of rejection has been made moot.

The second substantive ground of rejection is directed to Claims 15, 18, 19 and 23, which stand rejected, under 35 U.S.C. §102(c), as being anticipated by International Publication WO 98/24768 to Banyu Pharmaceutical Co., Ltd.

Without conceding the appropriateness of this ground of rejection, it is again emphasized that applicants need not address the substance of this ground of rejection insofar as the claims subject to this ground of rejection have been cancelled.

It is noted that dependent Claims 21 and 22 have not been made subject to any substantive grounds of rejection. As such, these claims are obviously in condition for allowance in view of the patentability of all the claims of the present application over the two formal grounds of rejection discussed supra.

In view of the cancellation of Claim 15, from which both Claims 21 and 22 depend, Claims 21 and 22 have been amended to incorporate those limitations of Claim 15 not originally explicitly included in Claims 21 and 22. That is, the scope of compounds synthesized in accordance with the processes of Claims 21 and 22 have been introduced into those claims.

It is emphasized that the amendments to Claims 21 and 22 do not affect the scope of these claims since the amendments thereto merely recites the limitations of these claims in independent form. The amendments to Claims 21 and 22, moreover, were not made in response to any rejection of these claims.

The above amendment and remarks establish the patentable nature of all the claims currently in this application. Notice of Allowance and passage to issue of these claims, Claims 1-3, 5-14, 21 and 22, is therefore respectfully solicited.

Respectfully submitted,

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